REMARKS

The above amendments and these remarks are responsive to the Office action dated September 17, 2004. Claims 1-16 are pending in the application. Claims 1-16 are rejected. By way of the present amendment claims 1 and 11 have been amended, claim 12 has been cancelled, and new claims 17-20 have been added. In view of the amendments above, and the remarks below, applicant respectfully requests reconsideration of the application under 37 C.F.R. § 1.111 and allowance of the pending claims.

Double Patenting Rejection

The Examiner provisionally rejected claims 1-16 under the judicially created doctrine of double patenting over claims 1-7 and 9-25 of copending Application No. 10/085,564 from which the present application is a continuation-in-part. Submitted herewith is a Terminal Disclaimer stating that this application and copending Application No. 10/085,564 are commonly owned by Bioject Inc., which overcomes the provisional rejection of claims 1-16 under the judicially created doctrine of double patenting.

Rejections under 35 USC §§ 102 and 103

Claim 1 and its Dependent Claims

Claim 1 stands rejected under 35 U.S.C. § 102(b) as being anticipated by Jacobsen et al. (U.S. Patent No. 5,833,632), March et al. (U.S. Patent No. 5,997,525), and Aldrich et al. (U.S. Patent No. 5,489,269); and under 35 U.S.C. § 102(e) as being anticipated by

Paskar (U.S. Patent No. 6,623,449) and Goll (U.S. Patent No. 6,344,027). Claims 2-6 and 8-10, which all depend directly or indirectly from claim 1, stand variously rejected under 35 U.S.C. § 102(b) and/or (e) based on the above five references. Claim 7 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over any of the above five references. As explained below, Applicant disagrees with the rejections but has nonetheless made certain claim amendments to clarify what Applicant regards as his invention.

Amended claim 1 calls for "an ejection mechanism adapted to eject the fluid from the fluid reservoir through the end effector and out of the injection orifice with sufficient pressure to penetrate the prostate gland while preserving functionality of the prostate gland." As stated on page 20 of the specification, "the injection pressure typically is selected so as to penetrate into the prostate without destroying its functionality." In general, as stated on page 8 of the specification, where "the intention is to inject into an internal organ, the pressure produced by system 10 ... must be adjusted so as not to destroy the functionality of the organ." Thus, "preserving functionality of the prostate gland" requires avoiding the use of excessive pressure. For example, as stated on page 2 of the specification, "use of an injection system that generates enough pressure to penetrate the outer dermal layer of the recipient on an internal organ might destroy at least some if not all of the functionality of the organ."

Referring first to the Jacobsen patent, Jacobsen does not disclose, teach or suggest

a needle-free jet injection device having "an ejection mechanism adapted to eject the fluid ... with sufficient pressure to penetrate the prostate gland while preserving functionality of the prostate gland," as described and claimed in the present application. Rather, as described at col. 4, lines 62-67 and col. 5, line 1, Jacobsen discloses a flexible catheter guide wire that merely allows medication "to leak from the bore of the guide wire into the vasculature passageway."

Referring next to the March patent, March does not disclose, teach or suggest a needle-free jet injection device having "an ejection mechanism adapted to eject the fluid ... with sufficient pressure to penetrate the prostate gland while preserving functionality of the prostate gland," as described and claimed in the present application. Rather, as described at col. 5, lines 21 to 25, March discloses a catheter that "is held in place for a suitable period of time, such as about 10 to about 300 seconds, allowing the agent to diffuse into the myocardium." Further as described at col. 5, lines 49 to 50, March teaches another embodiment of the catheter that is configured such that the "agent will then seep out [of] the material at the distal portion of the catheter and permeate into the heart wall."

Referring next to Aldrich patent, Aldrich does not disclose, teach or suggest a needle-free jet injection device having "an ejection mechanism adapted to eject the fluid ... with sufficient pressure to penetrate the prostate gland while preserving functionality of the prostate gland," as described and claimed in the present application. Rather, as

described at col. 1, lines 11-13, Aldrich discloses a drainage catheter that may be "introduced to a drainage site such as an abscess or a cavity in the biliary, nephrostomy, or urinary system."

Regarding the Paskar patent, Paskar does not disclose, teach or suggest a needle-free jet injection device having "an ejection mechanism adapted to eject the fluid ... with sufficient pressure to penetrate the prostate gland while preserving functionality of the prostate gland," as described and claimed in the present application. In contrast, as described at col. 12, lines 21-43, Paskar discloses a transformable catheter that may deliver "liquid, such as contrast media." Such liquid delivery may be made through "selective arterial injection" or "aortic and ventricular injections." See col. 12, lines 29-30 and 36-38. Paskar's catheter permits "pressure delivery of a large bolus of contrast media" for "midstream and ventricular opacification." See col. 12, lines 40-43. However, Paskar does not disclose, teach or suggest a pressure that is sufficient to "penetrate the prostate gland while preserving functionality of the prostate gland," as claimed in amended claim 1.

Referring now to the Goll patent, Goll does not disclose, teach or suggest a needle-free jet injection device having "an ejection mechanism adapted to eject the fluid ... with sufficient pressure to penetrate the prostate gland while preserving functionality of the prostate gland," as described and claimed in the present application. Rather, as described at col. 2, line 59 to col. 3, line 41, Goll discloses a high pressure injection catheter. Goll

teaches that the operating pressure of its catheter "must be sufficiently high to pierce the tissue," such as "in the range of 4000-7000 psi." See col. 4, lines 55-63. While Goll teaches at col. 7, lines 13-19 that the "degree of tissue trauma may be modified" by varying parameters such as applied pressure, Goll does not disclose, teach or suggest that excessive pressure should be avoided to preserve tissue functionality. Thus, Goll does not disclose, teach or suggest a pressure that is both sufficient to penetrate the prostate gland but also low enough to preserve functionality of the prostate gland, as claimed in amended claim 1.

Additionally, amended claim 1 calls for "a rigid end effector having a blunt distal end and including at least one injection orifice, the end effector being adapted to be positioned within a prostatic section of a patient's urethra adjacent the patient's prostate gland, wherein the injection orifice is oriented generally laterally to a longitudinal axis of the end effector" (emphasis added). As described in the specification, "needle-free injection systems are designed to eject the fluid from a fluid chamber with sufficient pressure to allow the fluid to penetrate the target." See page 1, lines 10-11. Therefore, in contrast to "standard fluid delivery systems that typically use a needle adapted to penetrate the outer surface of a target," a needle-free jet injection device is configured to deliver fluid into an internal organ without having the end effector penetrate the surface of the target organ. See page 1, lines 8-11.

In contrast, Goll does not disclose, teach or suggest an end effector having both "at

least one injection orifice ... oriented generally laterally to a longitudinal axis of the end effector" and "a blunt distal end," as described and claimed in the present application. Instead, as described at col. 6, lines 47-55 and shown in Figs. 6A-6D, Goll discloses injection catheters having an injection port oriented distally with either a blunt or sharpened distal end. In contrast, the only injection catheter that Goll discloses as having laterally oriented injection ports also has a sharpened distal end, as described at col. 6, lines 47-55 and shown in Fig. 6E. Further, as described at col. 7, lines 44-48, Goll teaches that the distal end of an injection catheter having a sharpened distal end (which may have laterally oriented injection ports) "is advanced a sufficient depth to position the injection port 26 just below the ... surface" of the organ. More particularly, at col. 6, lines 58-61, Goll teaches that "the sharpened end of the nozzle 26E [the injection catheter having laterally oriented injection ports 30E] penetrates the ... surface" of the organ "to deliver fluid therein." The Goll disclosure regarding lateral injection ports is limited to lateral injection ports used for subsurface fluid delivery from an injection catheter having a sharpened tip. Thus, Goll does not disclose, teach or suggest an injection catheter having both injection ports oriented laterally and a blunt distal end.

As discussed above, the cited references do not disclose, teach or suggest a device as claimed in amended claim 1. Claims 2-10 contain further limitations that distinguish the cited references. Accordingly, amended claim 1 and its dependent claims patentably

distinguish the cited art, and Applicant respectfully requests that the rejections of claims 1-10 under 35 U.S.C. §§ 102 and 103 be withdrawn.

Claim 11 and its Dependent Claims

Claim 11 stands rejected under 35 U.S.C. § 102(b) as being anticipated by Jacobsen et al. (U.S. Patent No. 5,833,632), March et al. (U.S. Patent No. 5,997,525), and Aldrich et al. (U.S. Patent No. 5,489,269); and under 35 U.S.C. § 102(e) as being anticipated by Paskar (U.S. Patent No. 6,623,449) and Goll (U.S. Patent No. 6,344,027). Claims 12-16, which all depend directly or indirectly from claim 11, stand variously rejected under 35 U.S.C. § 102(b) and/or (e) based on the above five references. Applicant disagrees with the rejections but has nonetheless made certain claim amendments to clarify what Applicant regards as the invention. For reasons similar to those stated above, Applicant respectfully submits that claims 11 and 13-16 patentably distinguish the cited references, and requests withdrawal of the rejections of those claims. Claim 12 has been cancelled, thus rendering the rejections moot insofar as they relate to claim 12.

Applicant has added new claim 17, which depends from claim 11. Support for the new claim can be found throughout the specification as filed and no new matter is added. Applicant believes that claim 11 is now allowable. Therefore, new claim 17 is similarly allowable.

New Claims 18-20

Applicant has added new independent claim 18 and dependent claims 19 and 20. Support for claims 18-20 may be found on pages 8-9 and 18 of the specification, in Figs. 5-9, and generally throughout the application as filed. No new matter is added. Applicant believes new claim 18 is allowable for at least the reasons stated above. New claims 19-20 depend from new claim 18. Applicant believes new claims 19-20 are similarly allowable for at least the reasons stated above.

Conclusion

Applicant believes that this application is now in condition for allowance, in view of the above amendments and remarks. Accordingly, Applicant respectfully requests that the Examiner issue a Notice of Allowability covering the pending claims. If the Examiner has any questions, or if a telephone interview would in any way advance prosecution of the application, please contact the undersigned attorney of record.

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, postage prepaid, to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 on March 17, 2005.

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